This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (twice amended) A method for detecting a polynucleotide in a breast sample comprising the steps of:

a) providing a probe, wherein said probe comprises at least 10 consecutive nucleotides in length, and which hybridizes ~~under highly stringent conditions~~ to a nucleic acid sequence comprising ~~given by~~ SEQ ID No:1 ~~or a fragment thereof~~;

b) contacting said sample with said probe and

c) quantifying the level of hybridization of said probe thereby determining the presence or amount of said polynucleotide in said sample wherein suppressed hybridization compared to control levels in surrounding breast tissue samples indicates the presence of a breast tumor.

Claim 2. (cancelled)

Claim 3. (withdrawn) A method for regulating a tumor, comprising the steps of:

a) providing a therapeutic composition comprising a polypeptide having the sequence of SEQ ID NO: 2; and

b) providing said therapeutic composition to said tumor.

Claim 4. (withdrawn) A method for regulating an adverse bodily reaction, comprising the steps of:

a) providing a therapeutic composition comprising a polypeptide having the sequence of SEQ ID NO: 2: and

b) providing said therapeutic composition to the area of adverse reaction.

Claim 5. (withdrawn) A method for detecting a tumor, comprising the steps of:

a) providing an antibody of a polypeptide comprising the sequence of SEQ ID NO: 2 or an antigenic fragment thereof;

b) contacting said probe to a sample of body fluid, tissue or tissue extract from a patient under a binding condition to produce a hybridized probe; and

c) quantifying the level of bound polypeptides.

Claim 6. (canceled)

Claim 7. (currently amended) A method for detecting a breast tumor in a subject characterized by an altered level of expression of MEC comprising: (a) contacting a breast sample expressing

mRNA polynucleotides with a probe that hybridizes to SEQ ID NO: 1 or a complement thereof ~~under stringent conditions~~; and (b) measuring the hybridization level of said probe to said polynucleotides, wherein reduced or loss of said mRNA expression levels compared to levels in breast samples without tumors surround the location of said tumor indicates the presence of a breast tumor in said subject.

Claim 8. (previously presented) The method of claim 7, wherein said measuring step is performed by Northern blot analysis, polymerase chain reaction (PCR), reverse transcriptase PCR, or in situ hybridization.

Claim 9. (previously presented) The method of claim 8 wherein said probe comprises a sequence of at least 10 consecutive nucleotides.

Claim 10. (previously presented) The method of claim 8 wherein said probe comprises a sequence of at least 20 consecutive nucleotides.

Claim 11. (previously presented) The method of claim 8 wherein said probe comprises a sequence of at least 50 consecutive nucleotides.

Claim 12 – 15 (canceled)

Claim 16. (currently amended) A method for detecting a breast tumor in a patient, comprising the steps of:
a) providing a probe the nucleotide sequence of which consists of SEQ ID NO: 1 or a fragment thereof;
b) contacting said probe to a sample of breast tissue or breast tissue extract from said patient ~~under highly stringent conditions~~ to permit hybridization of said probe to mRNA encoding a protein encoded by SEQ ID NO: 1 and
c) quantifying the level of hybridization of said probe to said mRNA wherein reduced or loss of said mRNA expression levels compared to levels in breast tissue adjacent to the location of said sample of breast tissue or breast tissue extract from said patient indicates the presence of a breast tumor in said patient.

Claim 17. (currently amended) The method of claim 16 wherein said ~~fragment~~ probe comprises a sequence of at least 10 consecutive nucleotides ~~unique to SEQ ID NO: 1~~.

Interview Summary

Applicants appreciate the telephonic interview with Examiner Holleran held on February 2, 2004. In that conference Applicants and Examiner discussed proposed amendments to Claims 1, 16 and 17 in order to place the application in condition for allowance.

Applicants and Examiner discussed the scope of Claim 1. Claim 1 is directed to a method for detecting a polynucleotide in a breast sample by providing a probe which hybridizes to an MEC nucleic acid sequence and quantifying the level of hybridization to determine the amount of MEC nucleic acid in the sample. First, Applicants proposed new amendments to Claim 1 to include claim language such as: "wherein suppressed hybridization compared to control levels in surrounding breast tissue samples indicates the presence of a breast tumor" which was inadvertently deleted by amendment and which places the claims in condition for allowance.

Subsequently, discussion was held regarding the laboratory manual reference ("Tijssen (1993) Laboratory Techniques in Biochemistry and Molecular Biology-Hybridization with Nucleic Acid Probes, part 1, chapter Discussion was held regarding the laboratory manual reference ("Tijssen (1993) Laboratory Techniques in Biochemistry and Molecular Biology-Hybridization with Nucleic Acid Probes, part 1, chapter 2, "Overview of principles of hybridization and the strategy of nucleic acid probe assays" Elsevier, New York") found in the specification on page 4 and the terms "stringent" or "highly stringent" in the claims. The Examiner proposed deletion in Claims 1 and 16 of the terms "stringent" or "highly stringent" from the claims. In order to advance prosecution, Applicants have deleted such language as recommended.

The Examiner also proposed amending Claim 1 to delete "or a fragment thereof" language. Claims 2, and 12-15 were cancelled by Applicant, thereby making rejections moot for these claims.

Applicants greatly appreciated the Examiners time and help during the interview. In view of the foregoing, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

If there are any fees due in connection with this communication, including any fees for a required extension of time, such an extension is requested and the Commissioner is authorized to charge the fees to Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
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(617) 871-3356

Date: 2/27/04

Regina Bautista
Attorney for Applicants
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Case No. 4-31360A/USN

Application No. 09/813,492

Mailing Date: March 1, 2004

Due Date: 3/12/04

Express Mail No.: EV335542827US

The Patent & Trademark Office acknowledges, and has stamped hereon the date of receipt of the items checked below:

- ☐ Amendment/Response/Letter - Fee $_____
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- ☐ PTO-1449 Form _____ Pg's
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- ☐ Application Data Sheet
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Initials

82972/99A Rev.1

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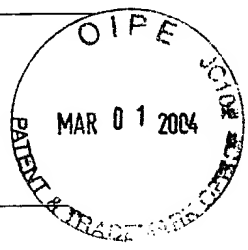

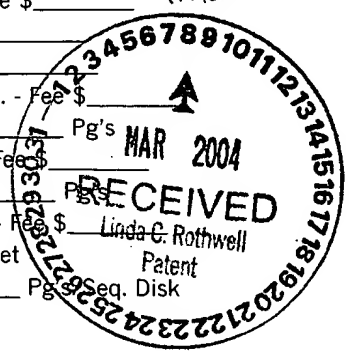

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